



Atty. Dkt. No. 069962-0102

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: CROOKS et al.

Title: ANALGESIC USES OF NORKETAMINE  
AND KETAMINE/NORKETAMINE  
PRODRUGS

Appl. No.: 10/714,643

Filing Date: November 18, 2003

Examiner: Yong Soo Chong

Art Unit: 1617

Confirmation 2532  
Number:

**Declaration Under 37 C.F.R. § 1.132**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. I, Mark S. Kleven, Ph.D., do hereby declare as follows.
2. My educational background, research experience, work experience, and professional memberships are described below.
3. My educational background is as follows:

Ph.D., Pharmacology, University of Minnesota School of Medicine, Minneapolis, MN, 1986. NIH Pre-Doctoral Fellow.

M.A., Physiological Psychology, Marquette University, Milwaukee, WI, 1979.  
B.A./B.S., Psychology, Biology/Applied Mathematics, Bemidji State University, Bemidji, MN, 1977. Honors Scholar (1974-1977); B.A., summa cum laude.

4. I have the following research experience and have published more than 70 peer reviewed articles, most in high impact journals.

In vivo/ex vivo neurochemistry, radioimmunoassay, immunohistochemistry, and receptor binding. Stereotaxic surgery (rats); in vivo brain microdialysis (rats); chronic indwelling cardiac catheters (rats and monkeys); ex vivo brain dissection (mice, rats and monkeys). In vivo, site-specific knock-down of gene expression using antisense and siRNA.

Operant behavior: conflict-procedure (pigeon); drug discrimination (mice, monkeys, pigeons, and rats); drug self-administration (monkeys, rats); conditioned avoidance responding (rats).

Unconditioned behavior: hypophagia (rats); stimulant-induced behaviors (mice, monkeys and rats); catalepsy (mice, monkeys and rats); 5-HT1A agonist-induced behaviors (rat); DOI-induced head twitches (rat); prepulse inhibition (rat); locomotor activity (mice, monkeys and rats), forced-swimming test (rat); tail suspension test (mouse); apomorphine-induced climbing (mouse); social-isolation (rat); dopamine-induced eye blinks (monkeys).

5. My work experience is as follows:

Yaupon Therapeutics, Inc. (2006-)

Vice President Preclinical Development

Direct GLP and non-GLP Efficacy, Safety, and Toxicology studies conducted primarily by CROs, but also by Yaupon staff, supporting IND submissions. Manage out-sourcing of IND-enabling Safety/Toxicology studies and have a key role for compiling new STTRs, IND and EMEA submissions. Am currently PI on an SBIR grant supporting a Phase I clinical trial for Attention Deficit Hyperactivity Disorder. Ongoing projects involve treatment of smoking cessation, methamphetamine abuse, ADHD, neuropathic pain, psoriasis, and cutaneous T-cell lymphoma.

Consultant (2005)

Behavioral Pharmacology / Preclinical development

University of Pennsylvania, Dept. of Psychology, Philadelphia, PA (2005-)

Visiting Scholar

Ongoing support and development of data gathering tools and analysis of in vivo electrophysiology and behavioral experiments. For example, assist in data analysis associating behavioral events with neuronal activity.

Scientific Commercialization LLC., (2004)

Principal, Head Early Phase R & D

Consulted and authored reports on treatment of coronary heart disease, e.g., aspirin resistance, antiplatelet activity of ADP inhibitors and PPAR- $\gamma$  agonists. Assisted advice for a critical sNDA review and developed leads for a new line of business.

Pierre Fabre Médicament, CASTRES, France (1992-2004)

Institute de Recherche Pierre Fabre

Pierre Fabre Médicament, the pharmaceutical branch of Groupe Pierre Fabre, is France's second-largest private drug firm, allocating 140 million euros (ca. 23% of revenues) to research and development.

Head, Behavioral Pharmacology, Neurobiology II (1992-2004)

Chargé de Mission, Fonction Support (2002-2004)

Directed pivotal in vivo studies leading to clinical development of more than six new chemical entities, (e.g., F15063 and others, e.g. eptapirone that are in Phase I-II clinical trials). Developed and implemented novel in vivo behavioral screening assays for schizophrenia, depression, and anxiety. Implemented in vivo gene-silencing constructs and intra-cranial delivery methods (e.g., siRNA and antisense).

The University of Chicago, Dept. of Pharmacological and Physiological Sciences,

Pritzker School of Medicine, Chicago, IL (1986-1992)

Assistant Professor (Research Associate (1989-1992)

Research Associate (1987-1989)

NIMH Post-Doctoral Fellow, Psychiatry (1986-1987)

Co-Principal Investigator on studies of pharmacological effects of acute and chronic cocaine in primates. Assisted direction of studies demonstrating the ability of dopamine D1 antagonists to block cocaine self-administration and its subjective effects in primates. Developed efficient behavioral methods in primates to test compounds for treatment of cocaine abuse. Principal Investigator on studies of cocaine neurotoxicity in rats. Characterized neurotoxic properties and structure-related activity of amphetamine-related compounds, such as the anorectic fenfluramine.

6. I am a member of the following professional organizations:

American Chemical Society,

American Society for Pharmacology and Experimental Therapeutics;

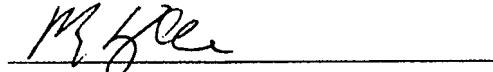
Collegium Internationale NeuroPsychopharmacologicum (Fellow);  
College on Problems of Drug Dependence (Industrial Relations Committee: 1997-  
2000);  
Drug Information Association;  
European College of Neuropsychopharmacology;  
European Behavioral Pharmacology Society (Executive Committee: 2001-2005);  
Society for Neuroscience

7. I am providing this Declaration with respect to the reference B. Ebert *et al.*, European Journal of Pharmacology, Aug. 20, 1997, 333 (1):99-104, ("Ebert *et al.*") which was cited in the Office Action dated July 9, 2007, for the above-captioned application.
8. In Ebert *et al.*, the last sentence states as follows: "Clinical studies are now under way to investigate whether orally administered (S)-norketamine may have fewer side effects than (S)-ketamine."
9. Ebert *et al.* has four authors: Bjarke Ebert, Soren Mikkelsen, Christian Thorkildsen and Finn Molke Borgbjerb.
10. I have searched the online PubMed database by the following author names: Ebert B., Mikkelsen S., Thorkildsen C., and Borgbjerb, FM. The results of these searches are attached hereto respectively as EXHIBITS 1-4. I have also searched the Ovid database.
11. Neither the search of PubMed nor the Ovid database indicated that any of the authors of Ebert *et al.* has made a subsequent publication related to clinical studies of (S)-norketamine or norketamine.
12. I am not aware of any publications related to clinical trials of (S)-norketamine or norketamine, or any requests for regulatory approval of the therapeutic use of (S)-norketamine or norketamine. Given my level of professional knowledge related to (S)-norketamine or norketamine, I would have known if there had been any publications related to clinical trials requests for regulatory approval of the therapeutic use of (S)-norketamine or norketamine.

13. Because over ten years has passed since the publication of Ebert *et al.*, and no public record of any clinical trials of (S)-norketamine or norketamine exists, I conclude that it is most certain that either (S)-norketamine was never tested in clinical trials, or if such clinical trials did occur, they were unsuccessful, discontinued and never publicized.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Dated: Oct 9, 2007



Mark S. Kleven, PhD

## EXHIBIT 1

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Items 1 - 155 of 155 One page.

**1:** [Friemel A, Ebert B, Hutson PH, Brust P, Nieber K, Deuther-Conrad W.](#) Related Articles, Links

 Postnatal development and kinetics of [(3)H]gaboxadol binding in rat brain: In vitro homogenate binding and quantitative autoradiography. *Brain Res.* 2007 Jul 20; [Epub ahead of print] PMID: 17692833 [PubMed - as supplied by publisher]

**2:** [Madsen C, Jensen AA, Liljefors T, Kristiansen U, Nielsen B, Hansen CP, Larsen M, Ebert B, Bang-Andersen B, Krogsgaard-Larsen P, Frolund B.](#) Related Articles, Links

 5-Substituted Imidazole-4-acetic Acid Analogues: Synthesis, Modeling, and Pharmacological Characterization of a Series of Novel gamma-Aminobutyric Acid(C) Receptor Agonists. *J Med Chem.* 2007 Aug 23;50(17):4147-61. Epub 2007 Jul 26. PMID: 17655213 [PubMed - in process]

**3:** [Vogensen SB, Frydenvang K, Greenwood JR, Postorino G, Nielsen B, Pickering DS, Ebert B, Bolcho U, Egebjerg J, Gajhede M, Kastrup JS, Johansen TN, Clausen RP, Krogsgaard-Larsen P.](#) Related Articles, Links

 A tetrazolyl-substituted subtype-selective AMPA receptor agonist. *J Med Chem.* 2007 May 17;50(10):2408-14. Epub 2007 Apr 25. PMID: 17455929 [PubMed - indexed for MEDLINE]

**4:** [Frolund B, Jensen LS, Storustovu SI, Stensbol TB, Ebert B, Kehler J, Krogsgaard-Larsen P, Liljefors T.](#) Related Articles, Links

 4-aryl-5-(4-piperidyl)-3-isoxazolol GABAA antagonists: synthesis, pharmacology, and structure-activity relationships. *J Med Chem.* 2007 Apr 19;50(8):1988-92. Epub 2007 Mar 22. PMID: 17375905 [PubMed - indexed for MEDLINE]

**5:** [Cremers T, Ebert B.](#) Related Articles, Links

 Plasma and CNS concentrations of Gaboxadol in rats following subcutaneous administration. *Eur J Pharmacol.* 2007 May 7;562(1-2):47-52. Epub 2007 Jan 19. PMID: 17362924 [PubMed - indexed for MEDLINE]

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site in the rat drug discrimination procedure.  
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PMID: 17361395 [PubMed - in process]

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Acad Radiol. 2006 Dec;13(12):1496-504.  
PMID: 17138118 [PubMed - indexed for MEDLINE]

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Phytochemicals induce breast cancer resistance protein in Caco-2 cells and enhance the transport of benzo[a]pyrene-3-sulfate.  
Toxicol Sci. 2007 Apr;96(2):227-36. Epub 2006 Oct 31.  
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GABA(A) receptor inhibition - site matters!  
Acta Physiol (Oxf). 2006 Nov-Dec;188(3-4):151. No abstract available.  
PMID: 17054654 [PubMed - indexed for MEDLINE]

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 Assessment of unspecific near-infrared dyes in laser-induced fluorescence imaging of experimental arthritis.  
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 Pharmacological characterization of agonists at delta-containing GABAA receptors: Functional selectivity for extrasynaptic receptors is dependent on the absence of gamma2.  
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 Identification of BCRP as transporter of benzo[a]pyrene conjugates metabolically formed in Caco-2 cells and its induction by Ah-receptor agonists.  
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 Upregulation of glutamate receptor subtypes during alcohol withdrawal in rats.  
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 Induction of gene expression of xenobiotic metabolism enzymes and ABC-transport proteins by PAH and a reconstituted PAH mixture in human Caco-2 cells.  
Biochim Biophys Acta. 2004 Nov 24;1681(1):38-46.  
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**29:** Krogsgaard-Larsen P, Frolund B, Liljefors T, Ebert Related Articles, Links

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 **Cell-specific protein profiling in *Arabidopsis thaliana* trichomes: identification of trichome-located proteins involved in sulfur metabolism and detoxification.**  
Phytochemistry. 2004 Jun;65(11):1641-9.  
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- 31: Sanchez C, Bogeso KP, Ebert B, Reines EH, Braestrup C.** Related Articles, Links  
 **Escitalopram versus citalopram: the surprising role of the R-enantiomer.**  
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- 32: Vestergaard HT, Vogensen SB, Madsen U, Ebert B.** Related Articles, Links  
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- 35: Voss J, Sanchez C, Michelsen S, Ebert B.** Related Articles, Links  
 **Rotarod studies in the rat of the GABAA receptor agonist gaboxadol: lack of ethanol potentiation and benzodiazepine cross-tolerance.**  
Eur J Pharmacol. 2003 Dec 15;482(1-3):215-22.  
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Mol Cell Neurosci. 2003 Sep;24(1):250-7.  
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 Pharmacology of GABA(A) receptors exhibiting different levels of spontaneous activity.  
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*Curr Top Med Chem.* 2002 Aug;2(8):817-32. Review.  
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*Brain Res.* 2002 Feb 1;926(1-2):94-107.  
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 Effects of GABA(A) receptor partial agonists in primary cultures of cerebellar granule neurons and cerebral cortical neurons reflect different receptor subunit compositions.  
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J Biomed Opt. 2001 Apr;6(2):134-40.  
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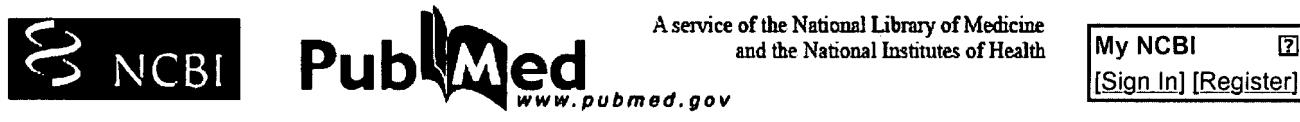
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